In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(E-Filed: April 30, 2008) No. 06-165V

LAIRD R. JONES and)	
SVITLANA V. BUDZHAK-JONES,)	TO BE PUBLISHED
legal representatives of a minor child,)	
WILLIAM OLEKSANDR JONES,)	Motion to Dismiss Petition
)	for Untimeliness; Petition
)	Alleging "Accumulative Mercury
Petitioners,)	Poisoning" that Led to an
)	Autism Spectrum Disorder;
v.)	Amended Petition Alleging
)	Significant Aggravation
SECRETARY OF THE DEPARTMENT)	
OF HEALTH AND HUMAN SERVICES,)	
)	
Respondent.)	
)	

Ruling on Respondent's Motion to Dismiss

On March 3, 2006, Laird Jones and Svitlana Budzhak-Jones, as the legal representatives of their minor child, filed a petition, while unrepresented by counsel, under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 to 34 (the "Vaccine Program"). See Petition (Petition) at 1. Petitioners seek compensation for injuries allegedly sustained by their son, William Oleksandr (William), following his receipt of a number of childhood vaccines administered on various dates between December 13, 2001, and April 11, 2003.

I. Procedural Background

As stated in the petition, William received the following vaccinations: the diptheria-tetanus-acellular pertussis vaccine (DTaP) on December 13, 2001, February 13,

¹ On July 12, 2006, about three months after petitioners filed their claim, Robert J. Krakow, Esq., entered his appearance as the attorney of record on behalf of petitioners.

2002, April 8, 2002, and April 11, 2003; <u>Haemophilus influenzae</u> type b/Hepatitis B vaccines (Hib/HepB) on December 13, 2001, February 13, 2002, October 9, 2002; inactivated polio virus (IPV) on December 13, 2001, February 13, 2002, April 8, 2002, April 11, 2003; measles, mumps, and rubella ("MMR") on October 9, 2002; pneumococcal conjugate (PCV) on December 13, 2001, February 13, 2002, April 8, 2002; and the varicella vaccine on October 9, 2002. <u>See</u> Petition at 1. Petitioners allege that their son suffered "accumulative mercury poisoning" that was caused in fact by his numerous vaccines. Id. at 1.

After holding an initial status conference to address a schedule for filings in this case, the undersigned issued an order summarizing the matters discussed during that status conference. See Order of 4/18/2006. Among the discussed matters during the status conference was petitioners' desire to have their claim included in the Omnibus Autism Proceeding (OAP). See id. Respondent requested that before permitting the transfer of the case to the OAP, the undersigned afford the parties an opportunity to address the issue of "whether the petition was timely filed, as some of the medical records report the onset of language regression more than 36 months prior to the filing of the petition." See id. The undersigned agreed to consider the timeliness issue first.

On June 14, 2006, respondent's counsel filed a Motion to Dismiss (R's Mot.). Petitioners' counsel requested an enlargement of time to file a response. On August 16, 2006, petitioners' counsel filed Petitioners' Memorandum in Opposition to Respondent's Motion to Dismiss (P's Opp.). In support of their opposition, petitioners attached to their filing an affidavit from Anne Carlson, Psy. D., the psychologist who diagnosed William with pervasive development disorder (PDD) in April 2004. See Dr. Carlson's Affidavit (Carlson Aff.).

² Consistent with the duties of a special master, set forth in Vaccine Rule 3(b), for determining how to conduct Program proceedings most efficiently, the Chief Special Master issued Autism General Order #1 on July 3, 2002, outlining the procedure for handling the anticipated filing of approximately 3000 to 5000 petitions alleging that certain administered childhood vaccinations were causing the neurodevelopmental disorder of autism or autism spectrum disorder in children. See Autism General Order #1 at 1-2. The coordinated proceedings addressing the numerous filed petitions seeking compensation for the alleged vaccine-related autistic spectrum disorders are referred to as the Omnibus Autism Proceeding (OAP). The underlying purpose of the OAP has been, and continues to be, to resolve the numerous filed petitions as expeditiously as possible. The procedure adopted for addressing the filed claims resulted from a number of meetings between the Chief Special Master and an informal advisory committee comprised of various petitioners' counsel and legal and medical representatives of the Secretary of the Department of Health and Human Services.

After the filing of petitioners' opposition to the motion to dismiss, the undersigned granted two requests from respondent for an enlargement of time to file a reply brief. On November 20, 2006, respondent's counsel filed Respondent's Reply to Petitioners' Memorandum in Opposition to Respondent's Motion to Dismiss (R's Reply). Together with the filing of the reply brief, respondent's counsel filed the expert opinion of Max Wiznitzer, M.D., a pediatric neurologist who, as part of his clinical practice, treats children with autism and neurodevelopmental disorders. See Respondent's Exhibit A (R's Ex. A).

Further to a telephonic status conference held to address further scheduling and possibly an onset hearing, the undersigned issued an Order on December 20, 2006. See Order of 12/20/06. The Order indicated that petitioners' counsel was considering retaining an additional expert to address the onset issue raised in the motion to dismiss. Id. The Order also indicated the undersigned's willingness to entertain a brief stay of proceedings to await a decision in the case of Markovich v. Secretary of Health and Human Services, 477 F.3d 1353 (Fed. Cir. 2007), that was then-pending before the Federal Circuit. Order of 12/20/06.

Nearly two months later, on February 9, 2007, the parties filed a Joint Status Report. The Joint Status Report indicated that petitioners were "in the process of retaining a medical expert to respond to respondent's medical expert, Max Wiznitzer, M.D., regarding the onset of William's Pervasive Developmental Disorder." Joint Status Report 2/9/07 at 1.

During a status conference held later in that month, the undersigned addressed the issuance of the Federal Circuit's decision in <u>Markovich</u>. See Order of 2/28/07. The subsequently issued Order dated February 28, 2007, stated that during the status conference, petitioners' counsel acknowledged that "the <u>Markovich</u> decision appeared to have found that <u>Setnes v. Sec'y of Health and Human Servs.</u>, 57 Fed. Cl. 175 (2003), was wrongly decided. Order of 2/28/07 at 1. Petitioners' counsel stated that his clients

³ In <u>Setnes</u>, the Court of Federal Claims determined that "[w]here there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the 'occurrence of the first symptom.'" <u>Setnes</u>, 57 Fed. Cl. at 179. The Court of Federal Claims reasoned that because the symptoms of autism develop "insidiously over time" and the child's behavior cannot readily be connected to an injury or disorder, the court's inquiry into the onset of the autistic condition is not limited to a determination of when the first symptom or manifestation of the condition occurred, but rather is informed by the child's subsequent medical or psychological evaluations of when the "manifestation of onset" occurred. <u>See id.</u> at 181.

were relying on a <u>Setnes</u> legal argument and on particular facts. <u>Id.</u> As further reflected in the issued Order, respondent has taken the position that <u>Markovich</u> has a strong bearing on this case because <u>Markovich</u> focuses "on the opinion of the medical community at large, and [requires the undersigned to determine] in this case, whether the medical community at large would deem the first symptom of pervasive developmental delay to have occurred in January of 2003." Order of 2/28/07 at 2. Respondent argued that petitioners' case "turns on whether petitioner can offer evidence that of William's documented speech regression in January 2003 did not constitute the first symptom or manifestation of his [PDD] disorder." Id.

By a Notice of Filing dated September 7, 2007, petitioners filed additional documents as supportive exhibits to Petitioners' Memorandum in Opposition to Respondent's Motion to Dismiss. See Petitioners' Notice of Filing (Ps' Notice). The additional documents included: (1) a declaration from Svitlana Budzhak-Jones, William's mother, designated as Petitioners' Exhibit 2; (2) the expert report of Daniela Stojanovich, Ph.D., designated as Petitioners' Exhibit 3; and (3) a medical article filed in support of Dr. Stojanovich's opinion, designated as Petitioners' Exhibit 4.⁴ Petitioners also filed a document identifying Yuval Shafrir, M.D., as an expert witness who would file another opinion on petitioners' behalf. Petitioners' Identification of Expert Witness filed 9/7/07.

On September 28, 2007, petitioners' counsel filed a Motion for Enlargement of Time for Submission of Expert Reports from Dr. Shafrir, requesting a thirty-day enlargement of time to file Dr. Shafrir's report "on the issue of 'manifestation of onset of symptoms' in connection with respondent's motion to dismiss the petition." See Petitioners' Motion for Enlargement of Time for Submission of Expert Reports at 1. The undersigned granted petitioners' counsel's request. See Order of 10/3/07 at 1.

On November 1, 2007, petitioners' counsel filed the expert report of Dr. Shafrir as Petitioners' Exhibit 5. On November 26, 2007, petitioners' counsel filed four medical articles in support of Dr. Shafrir's expert opinion.⁵ See Petitioners' Exhibits (Ps' Ex.) 6-

⁴ Usha Chavda, et al., <u>Important Issues in the Care and Evaluation of</u> Bilingual/Multilingual Children, 18:1 International Pediatrics 8 (2003).

Trends From United States Special Education Data, 115:3 Pediatrics e277 (2005); (2) Julia Daniels, Guest Editorial: Autism and the Environment, 114:7 Environmental Health Perspectives A396 (2006); (3) M.R. Herbert et al., Autism Environmental Genomics, 27 Neurotoxicology 671 (2006); and (4) Sven Bölte et al., Genetic, Environmental and Immunologic Factors in the Etiology of Autism Spectrum Disorders, 2 Neurolembryology 175 (2003). Subsequently, on

Further to a telephonic status conference on November 27, 2007, held for the purpose of addressing Dr. Shafrir's expert report, the undersigned issued an Order stating that "the relevant and binding case law does not focus on the diagnosis of autism but on the first manifestations of symptoms of the condition, and the experts for both parties agree that language regression may be a sign of autism." Order of 11/28/2007 at 1. During that status conference, the undersigned specifically inquired of petitioners' counsel whether petitioners had presented all of the evidence that petitioners intended to introduce in support of their opposition to respondent's motion to dismiss. See id. at 2. Petitioners' counsel represented that petitioners had completed their evidentiary presentation and advised that he would be filing an amended petition in the case. Id.

During that same November 2007 status conference, the undersigned also inquired of respondent's counsel whether respondent's counsel intended to file any rebuttal statements to address petitioners' filings. <u>Id.</u> at 2. Respondent's counsel stated that her client viewed the record as complete and that she did not anticipate filing any rebuttal opinions.

The undersigned discussed with the parties whether a fact hearing was necessary. <u>Id.</u> Petitioners' counsel stated that no new factual matters were expected to be presented during a hearing. The undersigned stated that in the absence of any new factual development, she viewed respondent's motion to dismiss as ripe for a ruling. The parties agreed.

Subsequently, on January 28, 2008, petitioners filed a Motion to Amend and Supplement Petition (P's Motion to Amend). The Amended Petition (Amended Petition) stated that

[i]n addition to the claims for compensation for vaccine injury, as presented in [petitioners'] petition filed [on] March 3, 2006 that, to the extent relevant, is incorporated by reference in this Amended Petition, petitioners claim that the vaccine administered on April 11, 2003, as reported on the record of vaccination submitted with the Petition as Exhibit Number 5 of their Petition, or the vaccine contents thereof, including thimerosal, significantly aggravated the illness, disability, injury or condition alleged in the Petition filed [on] March 3, 2006.

December 6, 2007, petitioners' counsel filed a curriculum vitae for Dr. Shafrir. See Ps' Ex. 10.

Amended Petition at 1. Petitioners stated in the Amended Petition that they were relying on the originally filed petition, the supporting affidavit from Dr. Carlson, and the subsequently filed documentation to support their claim that the administration of the April 11, 2003 vaccine aggravated William's condition. <u>Id.</u> at 2. Petitioners adopted the language of the Master Petition from the OAP and requested that their claim for compensation "be transferred to and included in the Omnibus Autism Proceeding." <u>Id.</u>

By Order of February 5, 2008, the undersigned directed that if respondent elected to respond to petitioners' motion to amend, respondent should address how, if at all, the motion to amend affected the pending motion to dismiss. On February 20, 2008, respondent's counsel telephonically contacted the court and indicated that she did not intend to file a response. The undersigned granted petitioner's motion to amend and supplement the petition.

II. The Factual Record⁶

William was born on October 6, 2001. Ps' Ex. 3 at 1-6. Throughout his first year of life, William was seen routinely for well-child medical care and immunizations. Ps' Ex. 4 at 1-6. During this time period, his growth and development were considered appropriate. Id. The medical records indicate that William had no specific immunization reactions, except for a note at his four-month visit on February 13, 2002, which states that he "cried for 2 hrs [after] shots." Ps' Ex. 4 at 3.

⁶ The facts addressed here are limited to those that are relevant to the jurisdictional issue of timeliness.

During his first year of life, William received the following vaccinations: DTaP on December 13, 2001, February 13, 2002, and April 8, 2002; the hepatitis B series, respectively, on December 13, 2001, February 13, 2002, and October 9, 2002; IPV on December 13, 2001, and February 13, 2002; and PCV on December 13, 2001, February 13, 2002, and April 8, 2002. See infra at page 2. On October 9, 2002, three days after his first birthday, William received a Hib/Hepatitis B combination vaccine, a varicella vaccine, and an MMR vaccine. On April 11, 2003, at eighteen months of age, he also received the IPV and DTaP vaccines. See Ps' Ex. 5.

⁸ The notes of subsequent well-child exams contain inconsistent histories regarding whether William had experienced an earlier vaccine reaction. An earlier vaccine reaction is noted by checkmark at William's fifteen-month visit (the record is unclear) and by a checkmark at his eighteen-month visit. Ps' Ex. 7 at 1, 2. At his six-month visit and his three-year visit, however, the absence of any earlier vaccine reaction is noted expressly. Ps' Ex. 4 at 4; Ps' Ex. 7 at 4. In any event, the records contain no indication that William experienced any reaction other than the crying episode reported at his four-month visit.

On January 10, 2003, at the age of fifteen months, William was seen for a well-child visit. Ps' Ex. 7 at 1. During this visit, William's pediatrician specifically noted regression in William's speech. Id. According to the pediatrician's assessment, William did not meet the developmental milestone for speech because he did not say "3 words other than mama/dada." Id. William's pediatrician elaborated that he "had words before but now regressed - not using." Id. The pediatrician noted further that William's "comprehension seems good at times but not always - good eye contact[,] no other skills regressed." Id. The physician's notations indicate that William had a language problem but no hearing difficulty or developmental delay. Id. The pediatrician added that William's parents "are trying to raise him as bilingual." Id. Due to the noted speech regression, however, the pediatrician recommended an evaluation by Early Intervention Services. Id.

Three months later, at William's well-child exam on April 11, 2003, William again failed to meet developmental milestones for speech. Ps' Ex. 7 at 2. He was unable to say "4-6 single words" or "tell 2 wants." <u>Id.</u> His diagnosis at this office visit was no longer speech regression but was speech "delay" and according to the pediatric notes, an "IEP" [individualized education plan]¹⁰ was "encouraged." <u>Id.</u> The physician's notes also reflect that William's "parents prefer to wait until 2 years." <u>Id.</u> The note suggests to the undersigned that notwithstanding the pediatrician's recommendation that the family take William for a further evaluation, the family expressed a preference for waiting.

⁹ In Pennsylvania, the state in which petitioners reside, Early Intervention Services refers to the system of services and support designed to help families with children who have developmental delays. See A Family's Introduction to Early Intervention in Pennsylvania, at http://www.pattan.k12.pa.us/files/EI/EarlyInt-guide-OUT.pdf (last visited April 24, 2008).

¹⁰ In Pennsylvania, an Individualized Education Program (IEP) must state a child's strengths and needs as well as the family's strengths and needs as they relate to the development of the child, including the strengths and needs identified in recent evaluations. A Family's Introduction to Early Intervention in Pennsylvania, at http://www.pattan.k12.pa.us/files/EI/EarlyInt-guide-OUT.pdf (last visited April 24, 2008). Generally, IEPs are designed to meet the needs of children from the age of three years until the child enters kindergarten. Id. IEPs are intended to supplant Individualized Family Service Plans (IFSPs), which have the same function and purpose as IEPs but are designed for families with children under the age of three years. Id. Based on the fact that William was eighteen months at the time this referral was made during the April 11, 2003 office visit, it is the view of the undersigned that the treating physician's intent was again to express concern regarding William's development and to direct the family to evaluation and support services within the community in which they lived.

Nonetheless, three months later, on July 25, 2003, William received a Multidisciplinary Evaluation (MDE) and an Individualized Family Service Plan (IFSP) for Early Intervention Services. Ps' Ex. 9 at 9. He qualified for services because he exhibited on evaluation "at least a 25% delay in one or more areas of development." Id.

The filed medical records include the following summary of his evaluation, excerpted here in relevant part:

Willy is a 21 month old child, raised in a multilingual household in a family with a history of delay of speech onset. He is showing delays in fine motor, cognitive, language, and social areas. . . . Willy has an unusual repetitive behavior of handflapping, which has been observed since very early. He is not showing communicative behaviors, either linguistic or nonverbal, typical for his age, and is at the less than one year age in this area.

<u>Id.</u> About a year after this evaluation, Anne Carlson, Psy.D, a licensed psychologist at MidStep Child Developmental Center evaluated William. Ps' Ex. 10. In her report of April 5, 2004, Dr. Carlson diagnosed William with Pervasive Developmental Disorder Not Otherwise Specified, ("PDD-NOS") and language delay. <u>Id.</u> at 3.

II. The Parties' Pending Motions

In the motion to dismiss, respondent asserts that because "this case was filed beyond the time limitations set forth in 42 U.S.C. § 300aa-16(a)(2), . . . the special master is without jurisdiction over the petition." R's Mot. at 1. Respondent argues that the undersigned's lack of jurisdiction over the case necessitates the denial of petitioners' request that the special master transfer this case into the OAP. See R's Mot. at 1-2. Instead of transferring the case, respondent contends, the undersigned must dismiss the case. See id.

In the filed Reply to Petitioners' Memorandum In Opposition to Respondent's Motion to Dismiss, respondent expands further on why petitioners have not met the jurisdictional requirements of section 16(a)(2) of the Vaccine Act. It is respondent's contention that William's diagnosis of speech regression at the January 10, 2003 pediatric office visit constituted the "first symptom or manifestation of onset" of William's PDD, and because the symptoms occurred more than three years before the filing of petitioners' action, petitioners' claim is time-barred and must be dismissed.

Petitioners challenge respondent's motion to dismiss on the ground that they do not believe that the speech regression that was diagnosed on January 10, 2003, constituted

the first symptom of William's PDD-NOS. Rather, petitioners argue, the petition was timely filed because the claim was brought within thirty-six months of the first manifestation of William's alleged vaccine injury. It is petitioners' position that the first manifestation of William's injury occurred when he was diagnosed at the age of thirty months with PDD.¹¹ See P's Mem. at 1.

Petitioners assert that William had no symptoms that would have triggered the statute of limitations prior to April of 2003. See id. at 2. Petitioners contend that the factual basis is lacking for respondent's assertion that the speech regression noted during William's January 10, 2003 pediatric visit constituted the "first symptom" or "manifestation of onset" of a neurodevelopmental disorder. Id. Petitioners argue that the diagnosis of "speech regression" and the pediatrician's recommendation for an early intervention evaluation cannot be relied upon as the events that triggered the running of the statute of limitations. See id.

III. The Applicable Law and Analysis

The Vaccine Act prohibits the filing of a petition for compensation for an alleged vaccine-related injury more than "36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury." 42 U.S.C. § 300aa-16(a)(2). As articulated by the Federal Circuit in the Markovich decision, for purposes of the Vaccine Act's limitations period, the "first symptom or manifestation of onset' . . . is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." Markovich v. Sec'y of Health and Human Servs., 477 F.3d 1353, 1360 (Fed. Cir. 2007). For petitioners' claim to be timely, the first sign of an alleged vaccine-related injury that was objectively recognizable by the medical profession at large must have occurred within thirty-six months of the filing date of the petition, which was March 3, 2006, in this case. Evidence that the first symptom of William's alleged vaccine injury occurred sometime prior to March 3, 2003, would render petitioners' claim of vaccine-related causation untimely.

A. The Offered Expert Opinions

Petitioners offered the affidavit of Dr. Anne Carlson in support of their position that the diagnosis of speech regression that William received on January 10, 2003, was

¹¹ Pervasive Developmental Disorder (PDD) and autistic disorder are defined as developmental disorders pursuant to criteria set forth in the Diagnostic & Statistical Manual, Fourth Edition, Text Revision (DSM-IV) of the American Psychiatric Association.

not the first symptom of William's PDD-NOS. In her affidavit, Dr. Carlson states:

Based on my review of William's history, medical records and upon my evaluation of William it is my opinion that the "speech regression" noted in the January 10, 2003 pediatric record cannot be determined to be the first symptom of what I later diagnosed in March 2004 to be a neurodevelopmental disorder classified as PDD.

Carlson Aff. ¶ 17. Dr. Carlson concedes that William's speech regression was recognized and identified as a problem by his treating pediatrician. But Dr. Carlson concludes that:

I cannot say and there is no way to determine, whether the speech regression observed in the January 10, 2003 examination was related to or was the precursor to the developmental disorder that William subsequently developed and with which he was diagnosed in April 2004. There is nothing in the medical record or history that would permit me to conclude that the speech regression noted on January 10, 2003, was the first symptom of William's PDD.

Carlson Aff. ¶¶ 18-19 (emphasis added).

Petitioners also filed an expert report from Daniela Stojanovich, Ph.D., a research associate professor at the Carleton University Institute of Cognitive Science in Canada. Dr. Stojanovich stated in her report that "[w]hile it is evident that William later developed a serious developmental disorder characterized in part by serious language regression and loss, I cannot say that the language delay observed at fifteen months [was] not normal." Ps' Ex. 3 at 6. Dr. Stojanovich supplied an article addressing particular considerations when evaluating children who are multilingual. See P's Ex. 4. The articles offered no insight, however, on the issue of how language regression in multilingual children with developmental disorders is distinguishable from language regression in monolingual children with developmental disorders.

In response to these filings from petitioners, respondent submitted an expert report from Dr. Wiznitzer, a pediatric neurologist. Dr. Wiznitzer disagreed with Dr. Carlson's conclusion that the speech regression identified on January 10, 2003, could not be found to be a symptom signaling the onset of William's PDD. R's Ex. A at 3. Dr. Wiznitzer stated in his report that "[s]peech/language regression is a well known early manifestation of PDD, occurring in approximately 15-40% of this population." <u>Id.</u> Dr. Wiznitzer added that speech regression "has been recognized as part of the diagnosis." <u>Id.</u> Dr. Wiznitzer explained that "language/speech regression is clearly a diagnostic feature of [the]

manifestation of autism/PDD and is unique to autism/PDD when it occurs with the other diagnostic features affecting socialization and communication [and it occurs] with associated restricted interests and/or other repetitive behaviors." <u>Id.</u> It is Dr. Wiznitzer's contention that a finding that William's diagnosed speech regression was an early symptom of his autistic spectrum disorder is appropriate "in this case because of the historical information that has been provided." <u>Id.</u>

Dr. Wiznitzer specifically challenged Dr. Carlson's assertion that "speech regression can be an early symptom of disorders that have nothing to do with the disorder with which William was eventually diagnosed." Carlson Aff. ¶ 22. He stated that "this statement is not supported by the literature that has been published on the topics of autism/PDD and language regression in childhood." R's Ex. A at 3. Moreover, Dr. Wiznitzer pointed out that in this particular case, there is "no evidence for any other condition that c[ould] cause speech/language regression such as hearing loss or epileptic aphasia." Id. at 4 (emphasis added). Based on the recognized relationship between language regression and autistic spectrum disorders, as well as the absence of another explanation for William's speech problem, Dr. Wiznitzer opined that "the conclusion that the pediatrician's note of 1/10/03 ([which] documented the occurrence of speech regression prior to that date) was a description or manifestation or sign of William Jones' pervasive developmental disorder" is proper and is supported by both William's submitted medical records and the published medical and psychology literature. Id.

To respond to Dr. Wiznitzer's opinion, petitioners filed the expert report of Yuval Shafrir, M.D., also a pediatric neurologist. Dr. Shafrir offered his view that the question posed here, "whether the first symptom of autism . . . appeared at or prior to 15 months of age, is beyond the scope of accurate clinical evaluation of autism, and beyond our current state of knowledge of this devastating condition." Ps' Ex. 5 at 1 (emphasis added). Dr. Shafrir acknowledges, however, his agreement with respondent's expert, Dr. Wiznitzer, that "language regression is a major sign in autism." Id. at 2 (emphasis added). From his opinion, it appears that Dr. Shafrir takes issue with any effort to pinpoint with exactness the time at which the symptoms of William's condition first became apparent. Citing testimony from the Cedillo hearing in the OAP, Dr. Shafrir noted the problems associated with efforts to determine the precise "time of onset of autism." See Ps' Ex. 5 at 3. Asserting that the onset of autism cannot be determined with precision, Dr. Shafrir opined that "the claim of Dr. Wiznitzer that the loss of [the] very few words that William had before or at the age of 15 months . . . show[ed] that he was already autistic or that the first symptoms of autism occurred at that time is [both] unsupported by the literature [Dr. Wiznitzer] cites, and unsupportable based on the current state of knowledge." Id. at 3.

Contrary to petitioners' assertions, however, any ambiguity concerning whether the

speech regression that was recognized at the January 10, 2003 doctor's visit was an early sign of William's injury is diminished by William's later diagnosis of PDD. Both parties' experts agree that language regression is a key symptom of autism. William's pediatrician documented his manifested language regression and there is no other explanation for William's loss of his acquired language. In this circumstance, it is more likely than not that William's observed language regression was a symptom of his subsequently diagnosed PDD.

Moreover, contrary to Dr. Shafrir's assertions, the timeliness inquiry required under the Vaccine Act does not attempt to fix with clinical certainty the onset of William's condition. Rather, the Act looks generally to when a symptom of or a manifestation of a vaccine-related problem first appeared. 42 U.S.C. 300aa-16(a)(2). And as the Federal Circuit has explained in Markovich, the medical significance of the first symptom or manifestation of an alleged vaccine-related injury need not be recognizable to lay persons (such as the parents of a child alleged to have suffered a vaccine-injury); instead, those first symptoms or manifestations of an injury must be recognizable "by the medical profession at large." Markovich, 477 F.3d at 1356, 1360.

Because the first symptom or manifestation of an injury is sufficient to trigger the statute of limitations, the running of the limitations period for a vaccine claim might begin sometime before petitioners have received an actual diagnosis of the alleged injury. As expressed by the Federal Circuit in Markovich, "the terms of the Vaccine Act demonstrate that Congress intended the limitations period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." Markovich, 477 F.3d at 1358.

In this case, the first indication of William's developmental disorder recognizable to his pediatrician was the regression of his speech. Based on the filed records, William's pediatrician expressed concern about William's loss of speech during the January 10, 2003 office visit. This particular record indicates that William's pediatrician was sufficiently concerned about William's language regression to make a referral for an early intervention evaluation during this fifteen-month well-child visit. See Ps' Ex. 7 at 1. Subsequently, at William's eighteen month pediatric visit, which occurred on April 11, 2003, his pediatrician made a similar recommendation. The pediatrician also made a record notation that the parents preferred to wait until William reached the age of two years before following up on the recommendation to obtain a further evaluation of

This is the same date, alleged in petitioners amended petition, on which William received a vaccination that significantly aggravated his condition.

William's development. See Ps' Ex. 7 at 2. The record in this case supports a finding that language regression, a key symptom of autism spectrum disorder, the condition with which William was later diagnosed, was apparent to William's pediatrician and was communicated to William's parents as early as January 10, 2003.

Section 16(a)(2) of the Vaccine Act requires that petitioners file their petition "within 36 months after the date of the occurrence of the first symptom or manifestation of onset." 42 U. S. C. § 300aa-16(a)(2). Based on the first appearance of a manifestation of William's condition at his pediatric visit on January 10, 2003, 13 petitioners must have filed their Vaccine Act claim no later than thirty-six months thereafter, or by January 10, 2006. Because this petition was not filed until March 3, 2006, nearly two months beyond the expiration date of limitations period, petitioners' filing is untimely with respect to the onset of William's PDD.

Special masters lack jurisdiction over untimely filed vaccine claims, and such claims must be dismissed.¹⁴ See Brice v. Health and Human Servs. (Brice I), 240 F.3d 1367, 1374 (Fed. Cir. 2001), cert. denied sub nom. Brice v. Thompson, 534 U.S. 1040 (2001) (equitable tolling is not available for claims arising under section 16(a)(2) of the Vaccine Act).

B. The Amended Petition

In addition to the claim that William received a series of vaccinations that caused "accumulative mercury poisoning" that ultimately led to the development of William's PDD, which petitioners alleged in the petition filed on March 3, 2006, petitioners have

¹³ It is quite likely that the regression of William's speech occurred prior to the noted speech regression on January 10, 2003. The pediatrician's assessment, however, establishes that the loss of speech was apparent by January 10, 2003. Because this assessment date precedes the filing of the petition by more than thirty-six months, this evidence of a manifested symptom is sufficient to trigger the dismissal of the case.

Vaccine Act, a special master cannot award attorneys' fees. See Brice v. Sec'y of Health and Human Servs. (Brice II), 358 F.3d 865, 868 (Fed. Cir. 2004)("The jurisdiction of the Court of Federal Claims to award attorneys' fees under the Vaccine Act is not unlimited. The court must have jurisdiction over a petitioner's claim for compensation before it can award attorneys' fees.")(emphasis added). See also Martin v. Sec'y of Health and Human Servs., 62 F.3d 1403, 1406-07 (Fed. Cir. 1995)(special master without "jurisdiction to award attorneys' fees and costs under the Vaccine Act if [special master] does not have jurisdiction to reach the merits of a claim for compensation").

advanced another claim in the amended petition contained in their motion filed on January 28, 2008. Petitioners allege in the amended petition that the DTaP vaccine administered to William on April 11, 2003 "caused a significant aggravation and exacerbation of the Autistic Spectrum Disorder that affects William." Amended Petition at 2.

The Vaccine Act provides that the statute of limitations is triggered either on the date of the first symptom or manifestation of onset or on the date of the significant aggravation of such injury. See 42 U.S.C. § 300aa-16(a)(2). The filing of a claim alleging a significant aggravation must occur with thirty-six months of the date of the alleged aggravation. Id. In this case, the administration of the vaccination alleged to have caused a significant aggravation of William's condition occurred within thirty-six months of the filing of petitioners' original Program petition. Accordingly, because this aspect of petitioners' action survives the timeliness bar, the undersigned transfers petitioners' significant aggravation claim to the OAP. 15

III. Conclusion

Petitioners' claim that William's received vaccinations caused his pervasive developmental delay-not otherwise specified is **DISMISSED** based on a finding that language regression, an early symptom of William's disorder, was apparent to William's pediatrician, was noted in his medical records, and was communicated to his parents more than thirty-six months prior to the filing of the petition. This claim is time-barred under the Vaccine Act.

Petitioners' claim of significant aggravation, which petitioners alleged in their amended petition, however, **SURVIVES** the jurisdictional challenge on the ground of timeliness. Consistent with petitioners' request, petitioners' significant aggravation claim is now part of the OAP.

¹⁵ The undersigned observes that at the time indicated by the Office of Special Masters, petitioners may be required to establish, that the vaccination William received on April 11, 2003, actually contained thimerosal. Moreover, petitioners may be required to establish that William experienced a significant aggravation of his condition that was caused by the received vaccination and was not due to a natural progression of his autistic spectrum disorder. As petitioners are aware, the Vaccine Act defines a significant aggravation as "any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4).

IT IS SO ORDERED.

s/Patricia Campbell-SmithPatricia E. Campbell-SmithSpecial Master